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10/506,429

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Tsutomu Furuzono

1035-526

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04/09/2007

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EXAMINER

PENG, KUO LIANG

ART UNIT

PAPER NUMBER

1712

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/506,429

Applicant(s)

FURUZONO ET AL.

Examiner

Kuo-Liang Peng

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/12/07 Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8 and 18 is/are allowed.
- 6) ☒ Claim(s) 9, 11, 13-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' amendment filed March 12, 2007 is acknowledged. Claims 19-20 are amended. Claims 10 and 12 are deleted. Now, Claims 1-9, 11 and 13-20 are pending.
2. The indicated allowability of Claims 9 and 11 is withdrawn in view of the new ground rejection over JP511 (JP 2001-172511), Sato (US 4 276 135) and Hino (US 5 814 681). Rejections based on the new ground follow.
3. The text of those sections of Title 35, U.S. code not included in this action can be found in prior Office Action(s).

#### ***Claim Rejections - 35 USC § 102***

4. Claims 9, 11, 13-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP511 (JP 2001-172511) as evidenced by Sato (US 4 276 135).

For Claims 9 and 11, JP511 discloses a hydroxyapatite complex prepared by a manufacturing method where a hydroxyapatite sintered compact is bonded to a polymer via urea or urethane linkages. The urea or urethane linkages can be derived from a reaction between an isocyanate functional group and an amino or

hydroxyl group. ([0011]-[0013], [0016], [0023], [0037] and [0043]) The hydroxyapatite can contain an amino group by treated with a silane coupling agent such as KBE903. ([0043] and [0049]) In addition, Sato teaches that KBE903 is **3-aminopropyl triethoxysilane**. The polymer can be surface treated to introduce active groups, followed by grafting through the active groups with ethylenic monomers containing functional groups for reacting with the hydroxyapatite. ([0044]) The polymers can be polysiloxane, etc. that are medical polymeric materials. ([0012] and [0044]) The hydroxyapatite complex can be used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047]) JP511 is silent on the use of the claimed **alkoxysilyl group**-containing polymer. However, the instant claims are product-by-process claims. “Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For Claims 13-17 and 19-20, as mentioned above, the hydroxyapatite sintered compact is treated with KBE903. As such, the hydroxyapatite complex comprises the structure (1) set forth in the instant claims.

5. Claims 9, 11, 13-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hino (US 5 814 681).

For Claims 9 and 11, Hino discloses a hydroxyapatite complex prepared by chemically bonding a hydroxyapatite sintered compact with a polymer. (col. 2, lines 8-49, col. 3, lines 29-34, col. 3, line 61 to col. 4, line 4) The hydroxyapatite can be surface treated using  **$\gamma$ -methacryloxypropyltrimethoxysilane**, etc. to afford polymerizable groups on the surface thereof. (col. 4, lines 5-39) The hydroxyapatite complex can be used as a medical material. (col. 1, lines 6-9) Hino is silent on the use of the claimed **alkoxysilyl group**-containing polymer.

However, the instant claims are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable

even though the prior product was made by a different process” In re Thorpe, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

For Claims 19-20, as mentioned above, the hydroxyapatite sintered compact is treated with  $\gamma$ -methacryloxypropyltrimethoxysilane. As such, the hydroxyapatite complex comprises the structure (1) set forth in the instant claims.

### ***Claim Rejections - 35 USC § 103***

6. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hino in view of JP511.

Hino discloses a medical material, *supra*, which is incorporated herein by reference. Hino is silent on the specific medical articles set forth in the instant claims. However, JP511 teaches a hydroxyapatite complex as a medical material used for preparing percutaneous trans-catheter, percutaneous terminal, artificial blood vessel and artificial organ. ([0047]) Note that Hino’s polymer contains polyoxyalkylene and methacryl moieties. (col. 2, lines 16-49) JP511’s polymer can contain polyoxyalkylene and poly(meth)acrylate.([0012]) Since Hino’s medical material is substantially the same as that of JP511’s, it would have been obvious to one of ordinary skilled in the art at the time of the invention was made

to utilize Hino's medical material for making JP511's medical articles with expected success. Especially, Hino is in the same field as that of JP511's endeavor.

*Allowable Subject Matter*

7. Claims 1-8 and 18 are allowed.

8. The following is an examiner's statement of reasons for allowance:


None of the above references, taken alone or in combination, teaches or fairly suggest a) the manufacture **method** of a hydroxyapatite complex where an **alkoxysilyl group**-containing polymer-based material is used as set forth in Claims 1-8; and b) the manufacture method of a hydroxyapatite complex where a hydroxyapatite sintered compact is reacted with an **isocyanate** group of **silk fibroin** as set forth in Claim 18.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on

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(571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp  
April 3, 2007

  
Kuo-Liang Peng  
Primary Examiner  
Art Unit 1712